



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,760	11/12/2001	Boaz Harari	687-456	1856

7590 06/06/2003
JEFFREY J. HOHENSHELL
AMERICAN MEDICAL SYSTEMS
10700 BREN ROAD WEST
MINNETONKA, MA 55343

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
----------	--------------

3732

DATE MAILED: 06/06/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,760

Applicant(s)

HARARI ET AL.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10, 11 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 11 and 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 3732

Election/Restrictions

Applicant's election with traverse of claims 1-4,10,11,20-26 in Paper No. 07 is acknowledged. The traversal is on the ground(s) that the restriction will require the applicant to file two additional applications to have all claims considered and that will represent substantial burden to the owners of the present application. This is not found persuasive because these inventions are distinct for the reasons given in the restriction and have acquired a separated status in the art as shown by their classification. However, applicant's argument with respect to claims 15-19 and 27,28 have been considered and found to be persuasive; therefore, these claims would be joined and examined with group I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,10,11,15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Romano (5,509,918).

With respect to claim 1, Romano discloses a bone boring device; as best seen in the figures, comprising: at least one needle (234,240) adapted for boring into bone a force providing element (100,102,182,184) remote from the needle, for advancing the needle; and a force amplifier (230,244) coupled to the needle and adjacent to the

Art Unit: 3732

needle which amplifies force provided from the force providing element and supplies it to the needle (234,240).

With respect to claims 2-4, Romano discloses all the limitations; as set forth in column 5, lines 50-67, column 6, lines 1-67; columns 7,8, lines 1-67; columns 12,13, lines 15-67; column 14, lines 1-40.

With respect to claims 10,11, Romano discloses a bone-boring device comprising at least one curved needle (234,240) adapted for extending to bore a hole in a bone, a base (174) holding the needle and adapted for being placed against a bone; a handle (20) coupled to the base, and a needle retractor (100,102,182,244) which retracts the needle when a force on the handle in a particular direction is lower than a predetermined amount prior to the base retreating from the bone in response to a lowering of the force; as set forth in columns 6-9, lines 1-67; and a needle advancer (100,102,182,244) which advances the needle only when a force on the handle in a particular direction is higher than a predetermined amount the predetermined force assuring that the base is urged against the bone; as set forth in columns 6-9, lines 1-67.

With respect to claim 15, Romano discloses a self-aligning device for boring into bone, comprising a boring head (234) having at least two boring tips (240) a body (182,184) a handle (20) attached to the body a hinge (242,246) coupling the head to the body at a location substantially equidistant from the boring tips; as best seen in 8.

With respect to claims 16-19, Romano discloses all the limitations, as set forth in columns 12,13,14 lines 1-67; and as best seen in FIGS 8-9C.

Art Unit: 3732

With respect to claims 20-22, the method steps, as set forth would have been inherently carried out in the operation of the device, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (5,269,785).

With respect to claims 23,28, it is noted that Bonutti discloses all the limitations, a drill bit (16, 122,123,130,132,138) for drilling into a bone and detecting a channel (36) formed therethrough and an aperture (128,136) from the outside of the bit to the channel; as best seen in FIGS14A-14E.

It is noted that Bonnuti did not teach of at least one needle adapted to fit through the aperture; as claimed by applicant. However, since applicant is not positively claiming the needle; a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Art Unit: 3732

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (5,269,785) in view of Romano (5,509,918).

With respect to claims 24-27, it is noted Bonutti did not teach of a drill bit comprising two drill bits, which are parallel and two needles that are curved; as claimed by applicant. However, in a similar art. Romano evidences the use of a boring device with two drill bits and needles that are parallel and curved for drilling a curved bore in an object.

Therefore, given the teaching of Romano, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the components of the device of Romano in the device of Bonutti to drill a curved bore in bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

4,345,601	08-1982	Fukuda
5,002,546	03-1991	Romano
4,312,337	01-1982	Donohue

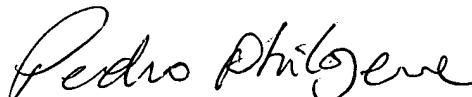
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

Art Unit: 3732

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
June 2, 2003


PEDRO PHILOGENE
PRIMARY EXAMINER